PATENT ABSTRACTS OF JAPAN

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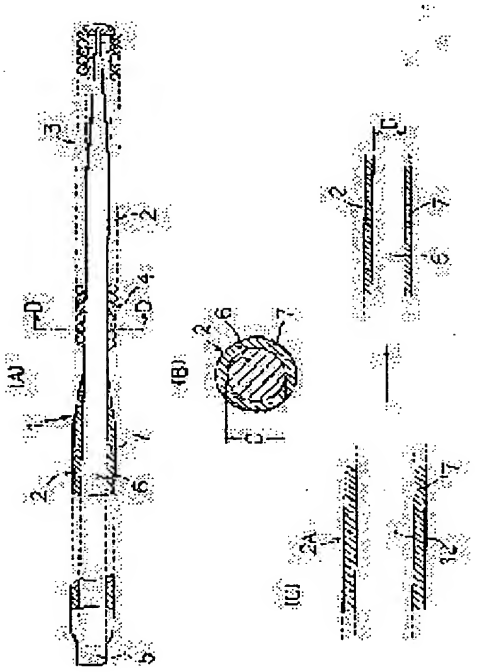
(54) MEDICAL GUIDE WIRE

(57)Abstract:
PROBLEM TO BE SOLVED: To provide a high-quality medical guide wire capable of further improving various mechanical properties such as vertical load performance, torsional rigidity, steering performance, bending performance and restorability from a bending state required for the guide wire and capable of adjusting and setting the various properties so as to fit for uses in the medical guide wire for fitting and installing a coil spring 4 to a tip part of a main wire rod 2 of a flexible slender linear body.
SOLUTION: The main wire rod 2 is constituted as a metallic two-layer structure integrally having a metallic thermal spraying layer 7 composed of a stainless steel material of a rigid alloy material on the outer periphery of a core wire rod 6 composed of an Ni-Ti wire of an ultraelastic alloy material or a metallic two-layer structure having the metallic thermal spraying layer 7 of an Ni-Ti alloy material on the outer periphery of the core wire rod 6 composed of a stainless steel wire. The guide wire 1 is characterized by being constituted as a one having high-quality performance or various specification quality by complementing and adjusting proper characteristics of the heterogeneous two-kinds metals.



* NOTICES *

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CLAIMS

[Claim(s)]
[Claim 1]In a medical-application guidewire which consists of principal ray material of long flexibility, this principal ray material, A medical-application guidewire to which it is made two-layer structure which provided a metallizing layer in a periphery of metallic core wire material, and said core wire material makes it superelastic alloy material, said metallizing layer uses a rigid alloy, said core wire material makes it a rigid alloy, and said metallizing layer is characterized by combination two-layer structure of superelastic alloy material **.
[Claim 2]Consist of principal ray material of long flexibility, and a coil spring in a medical-application guidewire which carried out fit-in arrival to a tip end part of this principal ray material a coil wire of said coil spring, A medical-application guidewire to which it is made two-layer structure which provided a metallizing layer in a periphery of metallic core wire material, and said core wire material makes it superelastic alloy material, said metallizing layer uses a rigid alloy, said core wire material makes it a rigid alloy, and said metallizing layer is characterized by combination two-layer structure of rigid alloy **.
[Claim 3]A medical-application guidewire of claim 1 which provided resin coating in a periphery of principal ray material.
[Claim 4]A medical-application guidewire of claim 1 which consists of principal ray material which carried out fit-in arrival of the coil spring to a tip end part of principal ray material, and exfoliated a metallizing layer of a part or all of this tip end part.
[Claim 5]A medical-application guidewire of claim 1 which consists of principal ray material which reduces the diameter of a large diameter bus line which provided a metallizing layer by wire drawing.
[Claim 6]A medical-application guidewire of claim 2 which carried out fit-in arrival of the coil spring which consists of a coil wire which reduced the diameter of a large diameter bus line which provided a metallizing layer by wire drawing.
[Claim 7]A medical-application guidewire of either claim 1 thru/or claim 6 whose metallizing layer is a laminated structure.
[Claim 8]A medical-application guidewire of either claim 1 thru/or claim 7 which consists of principal ray material or a coil spring which performed shape memory treatment.

[Translation done.]

* NOTICES *

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention]This invention relates to the medical-application guidewire used when introducing a catheter in a cardio-vascular system.
[0002]
[Description of the Prior Art]Insert the catheter of a super-thin flexible-tube object into a blood vessel for the purpose of angiography, or, Or in order to make insertion of the catheter safely reliable when inserting a balloon catheter in the therapy of the blockade part of coronary arteries into a blood vessel, The medical-application guidewire which consists of a flexible wire rod is used, and there is a well-known example shown in JP,4-25024,B and JP,4-292175,B.
[0003]And this medical-application guidewire 1 (only henceforth the guidewire 1), (Refer to drawing 7) Since it inserts in blood vessel 9 and the branching blood vessel 9A of the complicated course which made it the line gestalt which consists of the principal ray material 2 of a flexible extra fine wire, and wound from the tip part 3, Since it inserts into a blood vessel and is made to go on, flexible flexibility and the vertical-load nature (buckling-proof nature) to the load of a direction of movement being required, and rotating further the rear end part 5 located in the outside of the body, The advanced mechanical properties which have simultaneously the appropriate steering nature to the rotation which twists and can operate the direction of the intravascular tip part 3 by rigidity and operation of the rear end part 5 are required, and the tip part 3, Since the pliability and the stability from flexion deformity which are sufficient for functioning as a guidance part of blood vessel interpolation ON are needed, it has the basic structure which carried out fit-in arrival of the coil spring 4 to the principal ray material 2 made into the narrow diameter.
[0004]Namely, when inserting in the branching blood vessel 9A, for example, If it reaches near the turning point of the branching blood vessel 9A which should form the Puri Shape part 8 which carried out plastic deformation of some of the tip part 3 to "the shape of a character of **" by the fingertip etc., and should be inserted into a blood vessel, and the Puri Shape part 8 should insert, Operation which rotates the guidewire 1 and introduces the Puri Shape part 8 into the branching blood vessel 9A is performed, and the branching blood vessel 9A is made to carry out insertion advance of the guidewire 1 by the introductory operation. Therefore, a gestalt whose rigidity the tip part 3 makes the guidewire 1 the Takayoshi flexibility, and it tends to fabricate the Puri Shape part 8, and improves in the direction of the rear end part 5 is desired.
[0005]As mentioned above, the conventional guidewire has many things of the principal ray material 2 which consists of a superelastic alloy line of a nickel(nickel)-Ti (titanium) system, or SUS (stainless steel) material of a rigid alloy, It is used for the gestalt which made the principal ray material 2 open flume type voice, or carried out resin coating, such as Teflon (registered trademark) coating, carrying out. And as a well-known example which applies the intrinsic property of its nickel-Ti alloy and SUS material, and aims at improvement in the mechanical properties of the guidewire 1, "The guidewire which consists of the principal ray material 2 of the two-sort metal wire connection which connected the nickel-Ti alloyed wire and the SUS material line on the middle point of the line object longitudinal direction" shown in the provisional-publication-of-a-patent table No. 508538 [nine to] gazette, There is a thing of "the gestalt which dedicated the core wire of SUS material to nickel-Ti alloy tube-like object of the sheath body" shown in JP,8-000734,A.

[0006]
[Problem(s) to be Solved by the Invention]"However, the principal ray material 2 which the principal ray material 2 which consists of SUS material turns into from the nickel-Ti alloy "is made easy to crook (kink) and the stability from flex shape is [nickel-Ti] inferior although excelled in rigidity (it is inferior to kink-proof nature)" It excels in shape memory nature, And there is a" intrinsic property in which the rigidity (a twist and flexural rigidity) of what has the good stability from bending deformation is inferior, and what consists of independent construction material, such as this, becomes thin [a part of aforementioned required mechanical properties] and deficient.
[0007]And since the thing of a well-known example which performed resin coating becomes a mirror plane periphery of the growth material which carried out wire drawing from the structure which performed resin coating, it may be bad, and may twist under use, the adhesion of the core material and resin coating may produce exfoliation and omission of resin coating with - bending stress, and it is inferior to safety.
[0008]On the other hand, the thing of the annexation structure of said nickel-Ti alloyed wire and a SUS material line, Since connection connection of two kinds of the metal wire is carried out by a communication trunk member, the connection part serves as step shape expanded diameter shape, and spoils blood vessel interpolation ON nature, and the mechanical strengths of a joining segment run short, and moreover, the connection processing makes it complicated and it is inferior to a moldability. And the thing of the aforementioned "nickel-Ti alloy sheath body gestalt", Although it becomes a compound gestalt of a nickel-Ti alloy and SUS material, since a sheath body produces the modification welded by pressure to a core material with flexing resistance when it inserts in the crooked small tube from naturally a clear lance existing between a core material and a sheath body, The insertion resistance to a small tube uses size, it is hard to carry out inserting operation, and there is fear which cannot be inserted substantially. And shaping of the nickel-Ti tube-like object of the long barrel restricted in general to diameter =0.2 millimeter in outside diameter = 0.3 millimeter is made very difficult, and lacks in practicality.
[0009]This invention provides the quality guidewire which cancels the difficulty of the above conventional technology.
[0010]
[Means for Solving the Problem]"A guidewire of this invention which solves the above technical technical problem In a medical-application guidewire which consists of principal ray material of long flexibility, this principal ray material, A medical-application guidewire of the first invention to which it is made two-layer structure which provided a metallizing layer in a periphery of metallic core wire material, and said core wire material makes it superelastic alloy material, said metallizing layer uses a rigid alloy, said core wire material makes it a rigid alloy, and said metallizing layer is characterized by combination two-layer structure of superelastic alloy material **", [0011]"Consist of principal ray material of long flexibility, and a coil spring in a medical-application guidewire which carried out fit-in arrival to a tip end part of this principal ray material a coil wire of said coil spring, Make it two-layer structure which provided a metallizing layer in a periphery of metallic core wire material, said core wire material makes it superelastic alloy material, and said metallizing layer A rigid alloy, It is or a medical-application guidewire of the second invention to which said core wire material uses a rigid alloy, and said metallizing layer is characterized by combination two-layer structure of rigid alloy **."
[0012]Namely, a guidewire of this invention which consists of the aforementioned composition, Use the combination two-layer of heterogeneous 2 metal of superelastic alloy material represented by nickel (nickel)-Ti (titanium) alloy and a rigid alloy represented with SUS (stainless steel) material and piano wire, and. It consists of thought which aims at further improvement in required mechanical properties as a guidewire by a mutual supplement of the mechanical property of superelastic alloy material of heterogeneous 2 kinds, and a rigid alloy which constitutes by a metallizing layer which can generate an outer layer of the two-layer structure by a metallizing means, and constitutes two-layer [the].
[0013]And principal ray material and a coil wire of the two-layer structure form beforehand a bus line which provided a metallizing layer by a publicly known means in a large diameter wire rod, and, in the appropriate back, a wire drawing line which carries out wire drawing of the bus line, and is accomplished on a two-layer tectonic line-like object of a prescribed diameter is mainly used. And it may be made a gestalt which provides resin coating, such as Teflon, in principal ray material of said first invention, and a double layer metallizing layer gestalt which carries out regeneration of the metallizing layer in middle of a diameter reduction wire-drawing process of the aforementioned wire drawing, and carries out wire-drawing rework

as a mode of the aforementioned basic constitution.
[0014]
[Function]Since the guidewire of the first invention of said composition comprises principal ray material of the two-layer structure of "the superelastic alloy material which is excellent in the shape memory nature and the kink-proof nature of what lacks in rigidity", and "the rigid alloy which is excellent in the rigidity and the flexibility of the thing inferior to kink-proof nature", With the combination "size adjustment of a core material and sprayed layers" of "whether to make into sprayed layers whether to use a core material", the mutual supplement of the intrinsic property of heterogeneous 2 metal is carried out, and can perform further improvement in said required mechanical property, and the heterogeneous 2 kinds of alloys. Offer of the various quality guidewire which made it consistent with various blood vessel situation and therapy situations, and carried out adjustment setting of the mechanical property minutely is attained.
[0015]And since the metallizing layer presents the porous gestalt which uses the set gestalt of metal particles and makes a micro opening exist among particles, In order to raise blood vessel interpolation ON nature, the adhesion holdout of vantithrombotics, such as heparin used together with hydrophilic polymer and this which are given to the periphery of principal ray material, is good, and the further improvement in blood vessel interpolation ON nature and a clot-of-blood preventive effect can be promoted. With the remaining stress by wire drawing, according to the compressive force by wire drawing, the adhesion of core wire material and a metallizing layer improves, really [real] core wire material and a metallizing layer become a line, and function as the rigidity improvement as a wire rod, and the aforementioned complement operation can attain smoothly the two-layer structure principal ray material which performed the aforementioned wire drawing.
[0016]On the other hand, the guidewire of the second invention of said composition, Since the coil wire of said two-layer structure constitutes the coil spring fitted in a tip end part, Can perform further improvement in the mechanical properties for functioning as the guidance part of blood vessel interpolation ON, and satisfying good insertion nature and drawing nature into the blood vessel of flex shape, and. By the metallizing layer which exists in a coil wire periphery, the adhesion holdout of hydrophilic polymer improves and the aforementioned insertion nature and drawing nature carry out improvement stability much more.
[0017]
[Embodiment of the Invention]First, the guidewire 1 of the first shot Akiichi example is explained with reference to drawing 1. Namely, in the guidewire 1 provided with the tip part 3 which consisted of the principal ray material 2 of a flexible super-thin line object, made the narrow diameter the some length of the tip end part of the principal ray material 2, carried out fit-in arrival of the coil spring 4, and was made into the Takayoshi flexibility flexible gestalt, The principal ray material 2 except the tip part 3 is making the two-layer structure which formed "the metallizing layer 7 of the SUS material of a rigid alloy" in the periphery of the core wire material 6 which consists of a nickel-Ti alloy of superelastic alloy material.
[0018]"detailed -- the principal ray material 2 of this two-layer structure -- the periphery of the bus line 12 of nickel-Ti alloy of a large diameter (refer to drawing 1 (C)) -- high-speed thermal spraying of the SUS material droplet which carried out melting and which carried out grain refining with the gas frame was carried out, and it was made to adhere" -- the metallizing layer 7 (hereafter) by a publicly known metallizing means the sprayed layers 7 -- saying -- the principal ray material bus line 2A which formed membranes is fabricated, and the appropriate back, The outside diameter D which carries out diametral shrinkage machining of the principal ray material bus line 2A by publicly known wire drawing, and consists of a nickel-Ti alloy = it has in general two-layer structure which equipped the periphery of the 0.217-millimeter core wire material 6 with the sprayed layers 7 of the SUS material of 20-150-micron thickness (this example is 70 microns).
[0019]The tip part 3 of the principal ray material 2 is processed into the thin diameter section which carried out polish removal of the periphery containing the sprayed layers 7, and fit-in arrival of the coil spring 4 is carried out, and, as for the end of the rear end part 5 which takes out with a blood vessel interpolation ON state to the outside of the body, polish removal of the sprayed layers 7 is carried out.
[0020]Since the core wire material 6 and the SUS material sprayed layers 7 of nickel-Ti alloy are united and the guidewire 1 of the above drawing 1 example complements each mechanical properties, In the basis provided with appropriate flexibility and rigidity, the principal ray material 2 becomes the high quality which is excellent in torque transmission force and rotation transmission nature, and is excellent in the insertion nature and steering nature into a blood vessel. And since the tip part 3 of this drawing 1 example consists

of a gestalt which fitted the coil spring 4 in the principal ray material 2 of only a nickel-Ti alloy, Flexion deformity flattery nature when inserting into the crooked blood vessel, and the stability from flexion deformity are good, are excellent in the insertion advance function of the tip part 3 as an insertion guidance part into a blood vessel, and can insert even a blood vessel terminal easily, and there is no possibility of it being supplemented with the tip part 3 by the crooked blood vessel, drawing out by it, and becoming difficulty.

[0021]And since the sprayed layers 7 which form a periphery are porous gestalten, the adhesion holdout of hydrophilic polymer and the vantithrombotic given to a periphery a sake [on the blood vessel interpolation ON disposition of the guidewire 1] is good, and lubricity improves much more, and a clot-of-blood preventive effect can be promoted. And since the principal ray material 2 is wire-drawing-narrow-diameter--ization-processed, further complement and adjustment of mechanical properties, such as rigidity, are attained with the remaining stress by the wire drawing, and. The adhesion of the core wire material 6 and the sprayed layers 7 improves, both really [real] function as a thing, there is no possibility that the sprayed layers 7 may exfoliate with the flexion deformity stress of blood vessel interpolation ON, and safety can be secured.

[0022]Then, with reference to drawing 2, other examples of the guidewire 1 of the first invention are described. Namely, in what becomes a periphery of the metal core wire material 6 from the principal ray material 2 of two-layer structure which formed the sprayed layers 7, "core wire material 6 uses SUS material, the sprayed layers 7 consist of nickel-Ti alloy", the thing and two-layer construction material of the drawing 1 example are reverse combination, and the principal ray material 2 of this drawing 2 exists in the latter half of the tip part 3 in which the sprayed layers 7 fitted the coil spring 4. in addition -- the principal ray material 2 of this drawing 2 example also provides the metallizing layer of a nickel-Ti alloy in the SUS material bus line of a large diameter -- being appropriate -- back elastic processing is carried out and the diameter is reduced.

[0023]Since the portion which forms the Puri Shape part 8 consists of the principal ray material 2 of only SUS material, the thing of this drawing 2 example becomes easy to carry out processing of the Puri Shape part 8. And since the principal ray material 2 except the SUS material exposed portion serves as composite structure of a nickel-Ti alloy and SUS material, by the characteristic complement of both metal, it is made required and moderate mechanical properties can secure it good.

[0024]Next, other examples of the first invention are described with reference to drawing 3. Namely, in the guidewire 1 which formed the resin coating 10, such as Teflon coating polyamide polyurethane, a fluororesin, etc. which wraps in the principal ray material 2, This principal ray material 2 is also made into the two-layer structure which formed the sprayed layers 7 of SUS material in the periphery of the core wire material 6 of "nickel-Ti alloy like the thing of the drawing 2 example, and has structure to which only the tip part 3 carried out polish removal of the sprayed layers 7. And resin coating 10 is performed to the perimeter of this principal ray material 2.

[0025]Since the principal ray material 2 is the same two-layer structure as the drawing 1 example, the guidewire 1 of the above drawing 3 example can secure the good mechanical properties by same "the mechanical properties complement with a nickel-Ti alloy and SUS material" as the thing of the drawing 1 example. And since the adhesion adhesion of the resin coating 10 to the sprayed layers 7 of a surface porous form improves, there is no complicated possibility that the resin coating 10 may exfoliate even if it bends and repeats - bend return into a blood vessel, and safety improves.

[0026]Heat-treat simultaneously the principal ray material 2 shown in each above example at the time of strainer processing after the aforementioned wire drawing, and it performs linear shape memory processing of a nickel-Ti alloy, It is considered so that it can draw out and do in the shape in which the linear part containing the tip part 3 which presented flex shape within the blood vessel reverts to linear shape by itself, and "knee ****" does not remain.

[0027]Below, the guidewire of the second shot Akiichi example is explained with reference to drawing 4. That is, in the guidewire 1 which consists of the tip part 3 which carried out fit-in arrival of the coil spring 4 to the tip end part of the principal ray material 2, the coil spring 4 is formed with the coil wire 11 of the two-layer structure which formed the nickel-Ti sprayed layers 7 in the periphery of the core wire material 6 of SUS material. In detail, the coil wire 11 is the two-layer structure which formed the nickel-Ti sprayed layers 7 in the SUS material line of the large diameter, and carried out diametral shrinkage machining to it by wire drawing like the principal ray material 2 of the drawing 1 example, and has become a gestalt made

"to be a SUS material layer about a nickel-Ti alloyed wire and the sprayed layers 7 in the core wire material 6" if needed.

[0028]Since the coil spring 4 greatly contributed to the mechanical properties of the tip part 3 consists of the coil wire 11 of two-layer metal structure, the guidewire 1 of this drawing 4 example, It can fabricate like said example of the first invention to the further improvement in the mechanical properties of the tip part 3, and the tip part 3 of the various quality which carried out adjustment setting of the mechanical properties minutely by contents adjustment of the two-layer metal. And since the periphery of the coil spring 4 consists of the sprayed layers 7 of a porous form, the adhesion holdout of hydrophilic polymer is good, and draws out with the blood vessel insertion nature of the tip part 3, and a sex is improved and stabilized. Shape memory treatment is performed after coiling to this coil spring 4.

[0029]Then, other examples of the second invention are described with reference to drawing 5. Namely, in the thing using the coil wire of the same two-layer structure metal wire as the drawing 4 example, As for the coil spring 4 of this drawing 5, one third by the side of a tip becomes the coil wire 11C of radiopacity material, and the two-layer structure coil wire 11A as the drawing 4 example in which middle 1/3 is the same as for one third by the side of coil wire 11B and the back end of the nature material of single of a SUS material line (or nickel-Ti material line), Welding connection is carried out and three kinds of this coil wire constitutes the single coil spring 4.

[0030]The coil spring 4 makes the thing of the above drawing 5 example the 3 aforementioned zone gestalten, and the front end of the tip part 3 functions as a detection point by the radiation of an intravascular position, and. Since it consists of SUS material in which an omitted portion is crooked easily, it is easy to carry out formation of the Puri Shape part 8, and a rear end portion uses two-layer metal structure, the stability and rigidity by crookedness are held, each portion of the coil spring 4 carries out a performance assignment, and further improvement in many performances of the tip part 3 can be performed.

[0031]Next, with reference to drawing 6, other gestalten of principal ray material 2 and the coil wire 11 of the two-layer structure of the second invention are explained for a start. That is, double layer lamination of the metallizing layer 7 which consists of SUS material or a nickel-Ti alloy is carried out, and the two-layer structure shown in drawing 6 has the two-layer structure which consists of the metallizing layers 7A and 7B of this lamination form, SUS material, or the core wire material 6 of nickel-Ti wire. According to the two-layer structure of this drawing 6 gestalt, the characteristic operation by the metallizing layer 7 becomes remarkable much more. These laminated metal sprayed layers provide and carry out primary wire drawing of the primary sprayed layers 7A to a bus line periphery, in the appropriate back, they form the secondary sprayed layers 7B in that periphery, carry out secondary wire drawing to it, and are fabricated.

[0032]The guidewire of this invention is not limited to the aforementioned example, but may be made into the compound gestalt of the second invention for a start [of the coil wire 11 of the principal ray material 2 and the coil spring 4] which makes ** two-layer structure someday. And as superelastic alloy material, publicly known superelastic alloy material which added Fe-CO to nickel-Ti, such as ternary alloy material and a Cu-Zn-aluminum system alloy, may be used.

[0033]

[Effect of the Invention]As the above explanation, the guidewire of this invention, Since it has the principal ray material and coil spring structure which becomes a metal wire periphery from the wire rod of "the two-layer structure of superelastic alloy material and a rigid alloy" which provided the metallizing layer by a metallizing means, the mutual supplement of the characteristic of the heterogeneous two-sort alloy should be carried out, and it should provide as a guidewire -- "-- it vertical-load nature [flexibility and] - twists, many mechanical properties, such as rigidity, steering nature, and bending **** remains tightness [of a tip part]", are improved much more, and the further upgrading of a guidewire can be promoted.

[0034]By and the combination of the alloy of the two-layer structure and "adjustment of a core diameter and sprayed-layers thickness." Tune many aforementioned mechanical properties finely and shaping offer of the guidewire of various quality suitable for the terms and conditions "the blood vessel size, the vessel diameter way, the lesion strangulation degree, for [for adults] - children", etc. is attained, [which changes with each human bodies] Further improvement in improvement of the therapy nature and the curative effect of the blood vessel therapy by a guidewire can be aimed at. There are the above useful several effects.

[Translation done.]

* NOTICES *

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]The medical-application guidewire of the first shot Akiichi example is shown, and, as for the front view and (B), in (A), DD sectional view of (A) and (C) are the explanatory views of the forming process of the principal ray material.
[Drawing 2]The medical-application guidewire of other examples of the first invention is shown, and, as for the front view and (B), in (A), EE sectional view of (A) and (C) are FF sectional views of (A).
[Drawing 3]The medical-application guidewire of other examples of the first invention is shown, as for (A), it is the front view and (B) is CC sectional view of (A).
[Drawing 4]The medical-application guidewire of the second shot Akiichi example is shown, as for (A), it is the front view and (B) is CC sectional view of (A).
[Drawing 5]The medical-application guidewire of the second shot Akiichi example is shown, and, as for EE sectional view of (A), and (B), in the front view and (B), FF sectional view of (A) and (D) are [(A)] GG sectional views of (A).
[Drawing 6]The sectional view of other examples of the coil wire of the principal ray material and the second invention of the first invention
[Drawing 7]As for the conventional medical-application guidewire example and (A), the front view and (B) are the explanatory views of the directions for use.
[Description of Notations]
1 Medical-application guidewire
2 Principal ray material
3 Tip part
4 Coil spring
5 Rear end part
6 Core wire material
7 Metallizing layer
8 Puri Shape part
9 Blood vessel
10 Resin coating
11 Coil wire
12 Bus line

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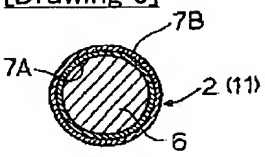
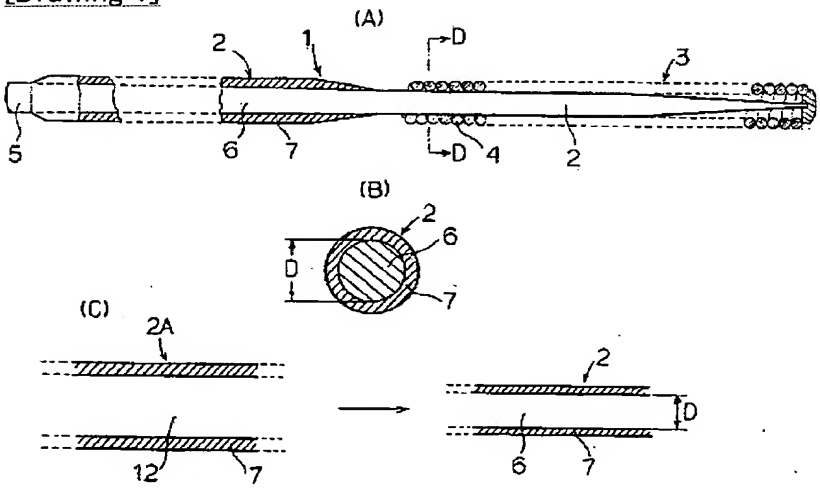
DRAWINGS

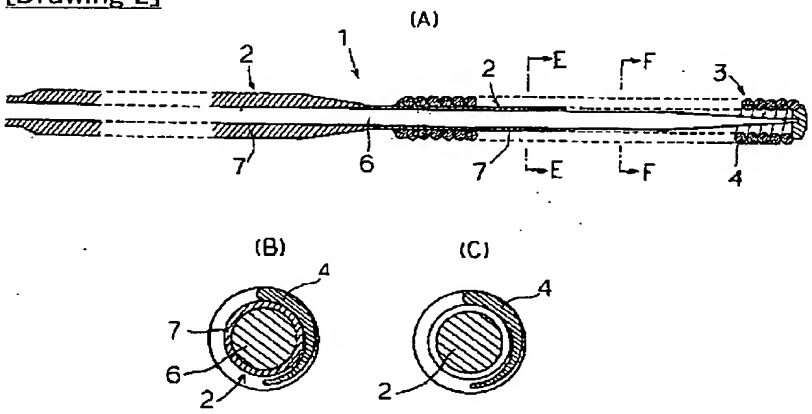
[Drawing 6]



[Drawing 1]



[Drawing 2]



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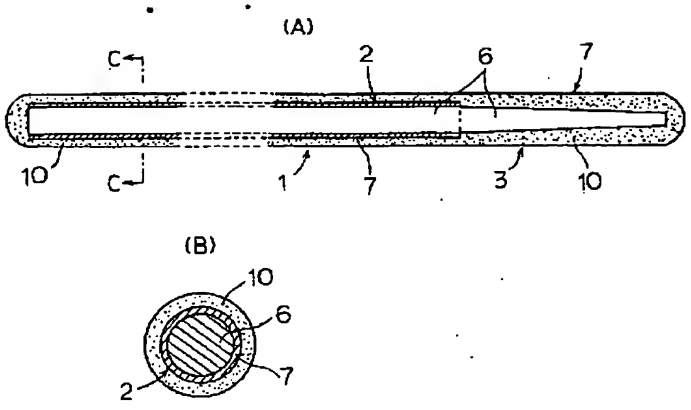

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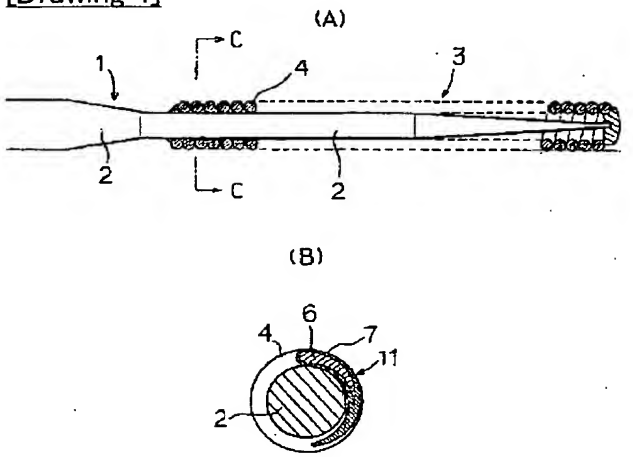
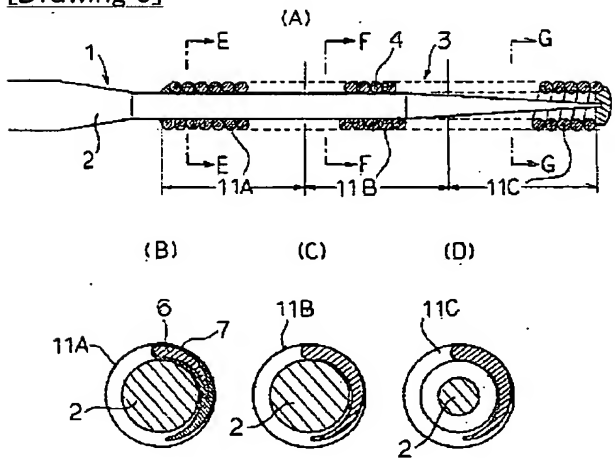
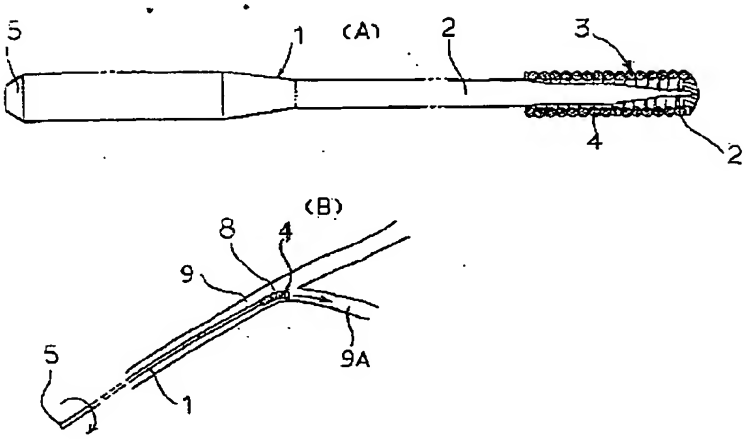


[Drawing 5]



[Drawing 7]



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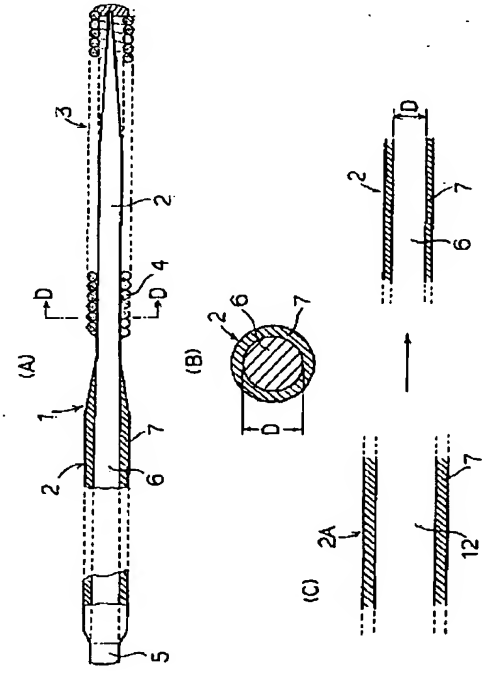
(54)【発明の名称】　医療用ガイドワイヤ

(57)【要約】
【課題】　可撓性細長線状体の主線材２の先端部分にコイルばね４を嵌装着した医療用ガイドワイヤにおいて、ガイドワイヤとして必要な「垂直荷重性・捩り剛性・ステアリング性・屈曲性・屈曲状態からの復元性」等の諸機械的性質のさらなる向上と、用途に整合した前記諸性質が調整設定できる高品質の医療用ガイドワイヤを提供する。
【解決手段】　主線材２が、超弾性合金材のＮｉ—Ｔｉ線からなる芯線材６の外周に剛性合金材のＳＵＳ材からなる金属溶射層7を一体に設けた金属２層構造、または、ＳＵＳ線からなる芯線材６の外周にＮｉ—Ｔｉ合金材の金属溶射層７を設けた金属２層構造に構成され、その異質２種金属の固有特性の補完・調整によって高品質性能のもの、または多様仕様品質のものに構成可能にしたガイドワイヤ１が特徴である。



【特許請求の範囲】
【請求項１】　長尺可撓性の主線材からなる医療用ガイドワイヤにおいて、該主線材は、金属質の芯線材の外周に金属溶射層を設けた２層構造にして、前記芯線材が超弾性合金材にして前記金属溶射層が剛性合金材、または、前記芯線材が剛性合金材にして前記金属溶射層が超弾性合金材、の組合せ２層構造を特徴とする医療用ガイドワイヤ。
【請求項２】　長尺可撓性の主線材からなると共に、該主線材の先端部分にコイルばねを嵌装着した医療用ガイドワイヤにおいて、前記コイルばねのコイル線は、金属質の芯線材の外周に金属溶射層を設けた２層構造にして、前記芯線材が超弾性合金材にして前記金属溶射層が剛性合金材、または、前記芯線材が剛性合金材にして前記金属溶射層が剛性合金材、の組合せ２層構造を特徴とする医療用ガイドワイヤ。
【請求項３】　主線材の外周に樹脂被覆を設けた請求項１の医療用ガイドワイヤ。
【請求項４】　主線材の先端部分にコイルばねを嵌装着し、かつ、該先端部分の一部または全部の金属溶射層を剥離した主線材からなる請求項１の医療用ガイドワイヤ。
【請求項５】　金属溶射層を設けた太径母線を、伸線加工によって縮径してなる主線材からなる請求項１の医療用ガイドワイヤ。
【請求項６】　金属溶射層を設けた太径母線を、伸線加工によって縮径したコイル線からなるコイルばねを嵌装着した請求項２の医療用ガイドワイヤ。
【請求項７】　金属溶射層が積層構造である請求項１ないし請求項６のいずれかの医療用ガイドワイヤ。
【請求項８】　形状記憶処理を施した主線材またはコイルばねからなる請求項１ないし請求項７のいずれかの医療用ガイドワイヤ。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、心臓血管系内にカテーテルを導入する際に用いる医療用ガイドワイヤに関するものである。
【０００２】
【従来の技術】血管造影を目的として、極細可撓管体のカテーテルを血管内に挿入したり、または、冠状動脈の閉塞部位の治療に、バルーンカテーテルを血管内に挿入するのに際し、そのカテーテルの挿入を安全確実にするために、可撓性線材からなる医療用ガイドワイヤが用いられており、特公平４－２５０２４号公報・特公平４－２９２１７５号公報に示される公知例がある。
【０００３】そして、この医療用ガイドワイヤ１（以下、単にガイドワイヤ１という）は、（図７参照）可撓性極細線の主線材２からなる線状形態にして曲りくねった複雑な径路の血管９・分岐血管９Ａに先端部３から挿入するので、柔軟な可撓性と進行方向の荷重に対する垂直荷重性（耐座屈性）が要求され、さらに、体外に位置する後端部５を回転させながら血管内へ挿入し進行させるので、その回転に対する応分の捩り剛性と、後端部５の操作によって血管内の先端部３の方向が操作できるステアリング性を併有する高度の機械的性質が必要であり、その先端部３は、血管内挿入の先導部として機能するに足る柔軟性と屈曲変形からの復元性が必要となるので、細径にした主線材２にコイルばね４を嵌装着した基本構造を有している。
【０００４】即ち、例えば分岐血管９Ａに挿入する場合は、先端部３の若干を指先等で「くの字状」に塑性変形させたプリシエイプ部８を形成して血管内に挿入し、そのプリシエイプ部８が、挿入すべき分岐血管９Ａの分岐点の近傍に達すると、ガイドワイヤ１を回転させてプリシエイプ部８を分岐血管９Ａに導入する操作が行われ、その導入操作によって、ガイドワイヤ１を分岐血管９Ａに挿入進行させることになる。従って、ガイドワイヤ１は先端部３が高可撓性にしてプリシエイプ部８が成形し易く、かつ後端部５の方向へ剛性が向上する形態が望まれる。
【０００５】以上から、従来のガイドワイヤは、Ｎｉ（ニッケル）－Ｔｉ（チタン）系の超弾性合金線または剛性合金材のＳＵＳ（ステンレス）材からなる主線材２のものが多く、その主線材２を露出形態にしたりテフロン（登録商標）コーティング等の樹脂被覆をした形態にして使用されている。そして、そのＮｉ－Ｔｉ合金材・ＳＵＳ材の固有特性を応用して、ガイドワイヤ１の機械的性質の向上を図る公知例として、特開表９－５０８５３８号公報に示される「Ｎｉ－Ｔｉ合金線とＳＵＳ材線を線体長手方向の中間ポイントで接続した２種金属線連結の主線材２からなるガイドワイヤ」と、特開平８－００７３４号公報に示される「ＳＵＳ材の芯線を鞘体のＮｉ―Ｔｉ合金筒状体に納めた形態」のものがある。
【０００６】
【発明が解決しようとする課題】しかし、ＳＵＳ材からなる主線材２は「剛性に優れるものの、屈曲（キンク）し易くして屈曲形状からの復元性が劣り（耐キンク性に劣る）」Ｎｉ－Ｔｉ合金材からなる主線材２は「形状記憶性に優れ、かつ曲げ変形からの復元性が良好であるものの、剛性（捩れ・曲げ剛性）が劣る」固有特性があり、これ等の単独材質からなるものは前記の必要機械的性質の一部が希薄・不備になる。
【０００７】そして、樹脂被覆を施した公知例のものは、伸線加工した伸材の鏡面外周に樹脂被覆を施した構造からなるので、その芯材と樹脂被覆との密着性が悪く、使用中の捩り・曲げ応力によって樹脂被覆の剥離・脱落を生ずることがあり、安全性に劣る。
【０００８】一方、前記Ｎｉ―Ｔｉ合金線とＳＵＳ材線の併合構造のものは、その２種類の金属線を接続管部材

によって接続連結するので、その連結部位が段差状の膨径形状となって血管内挿入性を損うと共に、連結部分の機械的強度が不足し、その上、その接続加工が煩雑にして成形性に劣る。そして、前記の「Ｎｉ—Ｔｉ合金材鞘体形態」のものは、Ｎｉ—Ｔｉ合金材とＳＵＳ材の複合形態になるものの、芯材と鞘体との間には当然にクリヤランスが存在することから、屈曲した細管へ挿入したときの曲げ抵抗によって鞘体が芯材へ圧接する変形を生ずるので、細管への挿入抵抗が大にして挿入操作がしづらく、実質的に挿入不能なるおそれがある。そして、概ね外直径＝０．３粍・内直径＝０．２粍に制限される長尺筒体のＮｉ—Ｔｉ筒状体の成形は極めて困難にして実用性に欠ける。

【０００９】本発明は、以上の従来技術の難点を解消する高品質ガイドワイヤを提供するものである。

【００１０】

【課題を解決するための手段】以上の技術課題を解決する本発明のガイドワイヤは「長尺可撓性の主線材からなる医療用ガイドワイヤにおいて、該主線材は、金属質の芯線材の外周に金属溶射層を設けた２層構造にして、前記芯線材が超弾性合金材にして前記金属溶射層が剛性合金材、または、前記芯線材が剛性合金材にして前記金属溶射層が超弾性合金材、の組合せ２層構造を特徴とする第一発明の医療用ガイドワイヤ」と、

【００１１】「長尺可撓性の主線材からなると共に、該主線材の先端部分にコイルばねを嵌装着した医療用ガイドワイヤにおいて、前記コイルばねのコイル線は、金属質の芯線材の外周に金属溶射層を設けた２層構造にして、前記芯線材が超弾性合金材にして前記金属溶射層が剛性合金材、または、前記芯線材が剛性合金材にして前記金属溶射層が剛性合金材、の組合せ２層構造を特徴とする第二発明の医療用ガイドワイヤ」になっている。

【００１２】即ち、前記の構成からなる本発明のガイドワイヤは、Ｎｉ（ニッケル）－Ｔｉ（チタン）合金に代表される超弾性合金材と、ＳＵＳ（ステンレス鋼）材・ピアノ線で代表される剛性合金材の異質２金属の組合せ２層にすると共に、その２層構造の外層を金属溶射手段によって生成できる金属溶射層によって構成し、その２層を構成する異質２種の超弾性合金材と剛性合金材の機械的特性の相互補完によってガイドワイヤとしての必要な機械的性質のさらなる向上を図る思想からなるものである。

【００１３】そして、その２層構造の主線材・コイル線は、太径線材に公知手段による金属溶射層を設けた母線を予め形成し、しかるのち、その母線を伸線加工して所定径の２層構造線状体に成す伸線加工線が主として用いられる。そして、前記の基本構成の態様として、前記第一発明の主線材にテフロン等の樹脂被覆を設ける形態や、前記の伸線加工の縮径伸線工程の中間において、金属溶射層を再生成して伸線再加工する複層金属溶射層形態にすることがある。

【００１４】

【作用】前記構成の第一発明のガイドワイヤは「剛性に欠けるものの形状記憶性・耐キンク性に優れる超弾性合金材」と「耐キンク性に劣るものの剛性・屈曲性に優れる剛性合金材」の２層構造の主線材で構成されるので、その異質２種類の合金材を「芯材にするか溶射層にするか」の組合せ「芯材と溶射層のサイズ調整」によって異質２金属の固有特性を相互補完して前記必要機械的特性のさらなる向上ができると共に、多様な血管事情・治療事情に整合させて機械的特性を微細に調整設定した多様品質ガイドワイヤの提供が可能になる。

【００１５】そして、その金属溶射層は、金属微粒子の集合形態にして微粒子間にミクロ空隙を存在させる多孔形態を呈するので、血管内挿入性を向上させるために主線材の外周に施す親水性ポリマー及びこれと併用するヘパリン等の抗血栓剤の付着保持性が良く、血管内挿入性のさらなる向上及び凝血防止効果が促進できる。さらに、前記の伸線加工を施した２層構造主線材は、伸線加工による残留応力によって線材としての剛性向上と、伸線加工による圧縮力によって芯線材と金属溶射層の密着性が向上して芯線材と金属溶射層が実質一体線になって機能し、前記の補完作用が円滑に達成できる。

【００１６】一方、前記構成の第二発明のガイドワイヤは、先端部分に嵌装するコイルばねを、前記２層構造のコイル線材によって構成するので、血管内挿入の先導部と機能して屈曲形状の血管内への良好な挿入性・引き抜き性を満足させるための機械的性質のさらなる向上ができると共に、コイル線外周に存在する金属溶射層によって親水性ポリマーの付着保持性が向上して、前記の挿入性・引き抜き性が一段と向上安定する。

【００１７】

【発明の実施の形態】まず、第一発明一実施例のガイドワイヤ１を図１を参照して説明する。即ち、可撓性極細線体の主線材２からなり、その主線材２の先端部分の若干長を細径にしてコイルばね４を嵌装着して高可撓性柔軟形態にした先端部３を備えたガイドワイヤ１において、その先端部３を除く主線材２は超弾性合金材のＮｉ—Ｔｉ合金からなる芯線材６の外周に「剛性合金材のＳＵＳ材の金属溶射層７」を設けた２層構造をなしている。

【００１８】詳しくは、この２層構造の主線材２は（図１（Ｃ）参照）太径のＮｉ—Ｔｉ合金の母線１２の外周に「ガスフレームで溶融させて細粒化したＳＵＳ材溶滴を高速溶射して付着させた」公知の金属溶射手段による金属溶射層７（以下、溶射層７という）を成膜した主線材母線２Ａを成形し、しかるのち、その主線材母線２Ａを公知の伸線加工によって縮径加工し、Ｎｉ—Ｔｉ合金材からなる外直径Ｄ＝概ね０．２１７粍の芯線材６の外周に、２０～１５０ミクロン膜厚（本実施例は７０ミク

ロン）のＳＵＳ材の溶射層７を備えた２層構造になっている。

【００１９】なお、その主線材２の先端部３は、溶射層７を含む外周を研磨除去した細径部に加工されてコイルばね４が嵌装着されると共に、血管内挿入状態で体外に出す後端部５の端は、溶射層７が研磨除去されている。

【００２０】以上の図１実施例のガイドワイヤ１は、Ｎｉ—Ｔｉ合金の芯線材６とＳＵＳ材溶射層７が一体となって、それぞれの機械的性質を補完するので、主線材２は応分の可撓性・剛性を備えた基において、トルク伝達力・回転伝達性に優れ、血管内への挿入性・ステアリング性に優れる高品質になる。そして、この図１実施例の先端部３はＮｉ—Ｔｉ合金材のみの主線材２にコイルばね４を嵌装した形態からなるので、屈曲した血管内へ挿入するときの屈曲変形追従性と屈曲変形からの復元性が良く、血管内への挿入先導部としての先端部３の挿入進行機能に優れ、血管端末まで容易に挿入できると共に、屈曲した血管によって先端部３が補足されて引き抜き困難になるおそれがない。

【００２１】そして、外周を形成する溶射層７が多孔形態であることから、ガイドワイヤ１の血管内挿入性向上のために外周に施す親水性ポリマー・抗血栓剤の付着保持性が良く、潤滑性が一段と向上すると共に凝血防止効果が促進できる。そして、主線材２が伸線細径化加工されているので、その伸線加工による残留応力によって剛性等の機械的性質のさらなる補完・調整が可能になると共に、芯線材６と溶射層７の密着性が向上して両者が実質一体物として機能し、血管内挿入の屈曲変形応力によって溶射層７が剥離するおそれはなく安全性が確保できる。

【００２２】続いて、図２を参照して第一発明のガイドワイヤ１の他の実施例を説明する。即ち、金属製芯線材６の外周に溶射層７を設けた２層構造の主線材２からなるものにおいて、この図２の主線材２は「芯線材６がＳＵＳ材にして、溶射層７がＮｉ—Ｔｉ合金材」からなり、図１実施例のものと２層材質が逆組合せであり、かつ、溶射層７がコイルばね４を嵌装した先端部３の後半部分に存在している。なお、この図２実施例の主線材２も、太径のＳＵＳ材母線にＮｉ—Ｔｉ合金材の金属溶射層を設け、しかるのち伸縮加工されて縮径されている。

【００２３】この図２実施例のものは、プリシエイプ部８を形成する部分がＳＵＳ材のみの主線材２からなるので、プリシエイプ部８の加工がし易くなる。そして、そのＳＵＳ材露出部分を除く主線材２はＮｉ—Ｔｉ合金材とＳＵＳ材の複合構成となるので両金属の特性補完によって必要にして適度な機械的性質が良好に確保できる。

【００２４】次に、図３を参照して第一発明の他の実施例を説明する。即ち、主線材２を包み込むテフロンコーティング・ポリアミド・ポリウレタン・ふっ素樹脂等の樹脂被覆１０を設けたガイドワイヤ１において、この主線材２も図２実施例のものと同様に「Ｎｉ—Ｔｉ合金材の芯線材６の外周にＳＵＳ材の溶射層７を設けた２層構造にして、先端部３のみが溶射層７を研磨除去した構造になっている。そして、この主線材２の全周に樹脂被覆１０が施されている。

【００２５】以上の図３実施例のガイドワイヤ１は、主線材２が図１実施例と同一の２層構造であることから、図１実施例のものと同様な「Ｎｉ—Ｔｉ合金材とＳＵＳ材との機械的性質補完」による良好な機械的性質が確保できる。そして、表面多孔質形態の溶射層７への樹脂被覆１０の付着密着性が向上するので、血管内において複雑な曲げ・曲げ戻しを反復しても樹脂被覆１０が剥離するおそれがなく、安全性が向上する。

【００２６】なお、以上の各実施例に示す主線材２は前記の伸線加工後のストレーナー加工のとき同時に熱処理してＮｉ—Ｔｉ合金材の直線形状記憶処理を施し、血管内で屈曲形状を呈した先端部３を含む線状部分が自力で直線形状に復元して「曲りぐせ」が残存しない形状で引き抜きできるよう配慮されている。

【００２７】つぎに、図４を参照して第二発明一実施例のガイドワイヤを説明する。即ち、主線材２の先端部分にコイルばね４を嵌装着した先端部３からなるガイドワイヤ１において、コイルばね４がＳＵＳ材の芯線材６の外周にＮｉ—Ｔｉ溶射層７を設けた２層構造のコイル線１１によって形成されている。詳しくは、コイル線１１は図１実施例の主線材２と同様に、太径のＳＵＳ材線にＮｉ—Ｔｉ溶射層７を設けて伸線加工によって縮径加工した２層構造であり、必要に応じて「芯線材６をＮｉ—Ｔｉ合金線・溶射層７をＳＵＳ材層」にする形態になっている。

【００２８】この図４実施例のガイドワイヤ１は、先端部３の機械的性質に大きく寄与するコイルばね４が２層金属構造のコイル線１１からなるので、第一発明の前記実施例と同様に先端部３の機械的性質のさらなる向上と、その２層金属の内容調整によって機械的性質を微細に調整設定した多様品質の先端部３に成形できる。そして、コイルばね４の外周が多孔質形態の溶射層７からなるので、親水性ポリマーの付着保持性が良く、先端部３の血管挿入性と引き抜き性が向上し安定する。なお、このコイルばね４は、コイリング後に形状記憶処理が施される。

【００２９】続いて図５を参照して、第二発明の他の実施例を説明する。即ち、図４実施例と同様な２層構造金属線のコイル線を用いるものにおいて、この図５のコイルばね４は先端側の１／３が放射線不透過材のコイル線１１Ｃ・中間の１／３がＳＵＳ材線（またはＮｉ—Ｔｉ材線）の単質材のコイル線１１Ｂ・後端側の１／３が図４実施例と同一の２層構造コイル線１１Ａになり、この３種類のコイル線が溶着連結されて単一のコイルばね４を構成している。

【００３０】以上の図５実施例のものはコイルばね４が前記の３ゾーン形態にして、先端部３の前端が血管内位置の放射線による検知ポイントとして機能すると共に、中間部分が屈曲し易いＳＵＳ材からなるので、プリシエイプ部８の形成がし易く、後端部分が２層金属構造にして屈曲による復元性・剛性を保有し、コイルばね４の各部分が性能分担して先端部３の諸性能のさらなる向上ができる。

【００３１】次に図６を参照して第一第二発明の２層構造の主線材２・コイル線材１１の他の形態を説明する。即ち、図６に示す２層構造はＳＵＳ材またはＮｉ—Ｔｉ合金材からなる金属溶射層７が複層積層され、この積層形態の金属溶射層７Ａ・７ＢとＳＵＳ材またはＮｉ—Ｔｉ線の芯線材６からなる２層構造を有している。この図６形態の２層構造によると金属溶射層７による特有作用が一段と顕著になる。なお、この積層金属溶射層は母線外周に一次溶射層７Ａを設けて一次伸線加工し、しかるのち、その外周に二次溶射層７Ｂを設けて二次伸線加工して成形される。

【００３２】なお、本発明のガイドワイヤは前記の実施例に限定されず、主線材２とコイルばね４のコイル線１１のいずれもを２層構造にする第一第二発明の複合形態にすることがある。そして、超弾性合金材としては、Ｎｉ—ＴｉにＦｅ・ＣＯを加えた三元系合金材、Ｃｕ—Ｚｎ—Ａｌ系合金材等の公知の超弾性合金材を用いることがある。

【００３３】

【発明の効果】以上の説明のとおり、本発明のガイドワイヤは、金属溶射手段によって金属線外周に金属溶射層を設けた「超弾性合金材と剛性合金材の２層構造」の線材からなる主線材・コイルばね構造を有するので、その異質２種合金材の特性を相互補完して、ガイドワイヤとして具備すべき「可撓性・垂直荷重性・捩り剛性・ステアリング性および先端部の曲げぐせ残留防止性」等の諸機械的性質を一段と向上して、ガイドワイヤのさらなる品質向上が促進できる。

【００３４】そして、その２層構造の合金材の組合せと「芯材径・溶射層厚さの調整」によって、前記の諸機械的特性を微調整して、個個の人体によって異なる「血管サイズ・血管径路・病変狭窄度・大人用・子供用」等の諸条件に適する多様品質のガイドワイヤの成形提供が可能となり、ガイドワイヤによる血管治療の治療性・治療効果の一段の改良向上を図ることができる。以上の有用な諸効果がある。

【図面の簡単な説明】

【図１】第一発明一実施例の医療用ガイドワイヤを示し、（Ａ）はその正面図、（Ｂ）は（Ａ）のＤＤ断面図、（Ｃ）はその主線材の成形方法の説明図

【図２】第一発明の他の実施例の医療用ガイドワイヤを示し、（Ａ）はその正面図、（Ｂ）は（Ａ）のＥＥ断面図、（Ｃ）は（Ａ）のＦＦ断面図

【図３】第一発明の他の実施例の医療用ガイドワイヤを示し、（Ａ）はその正面図、（Ｂ）は（Ａ）のＣＣ断面図

【図４】第二発明一実施例の医療用ガイドワイヤを示し、（Ａ）はその正面図、（Ｂ）は（Ａ）のＣＣ断面図

【図５】第二発明一実施例の医療用ガイドワイヤを示し、（Ａ）はその正面図、（Ｂ）は（Ａ）のＥＥ断面図、（Ｂ）は（Ａ）のＦＦ断面図、（Ｄ）は（Ａ）のＧＧ断面図

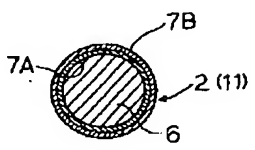
【図６】第一発明の主線材・第二発明のコイル線の他の実施例の断面図

【図７】従来の医療用ガイドワイヤ示し、（Ａ）はその正面図、（Ｂ）はその使用方法の説明図

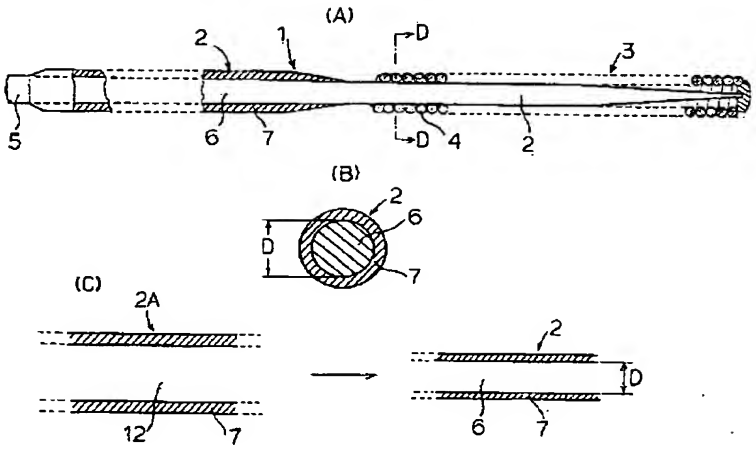
【符号の説明】

１　医療用ガイドワイヤ
２　主線材
３　先端部
４　コイルばね
５　後端部
６　芯線材
７　金属溶射層
８　プリシエイプ部
９　血管
１０　樹脂被覆
１１　コイル線
１２　母線

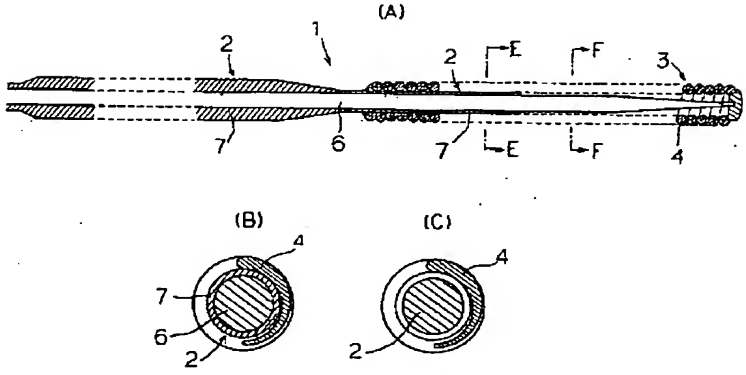
【図６】



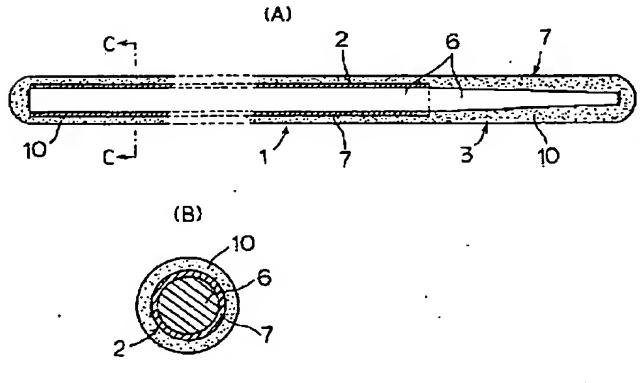
【図１】


(A)
2
1
D
3
5
6
7
D
4
2
(B)
2
6
D
7
(C)
2A
2
D
12
7
6
7

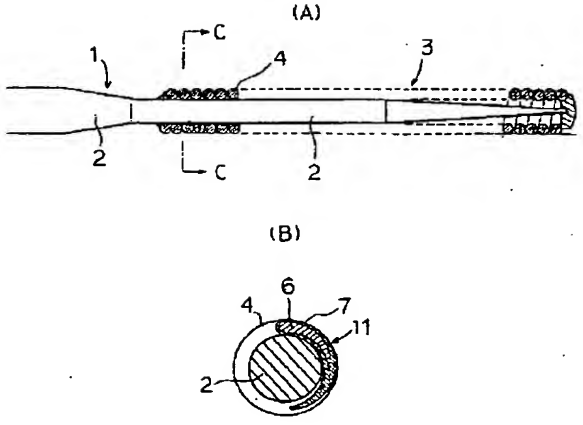
【図２】


(A)
2
1
2
E
F
3
7
6
7
E
F
4
(B)
(C)
4
7
6
2
4
2

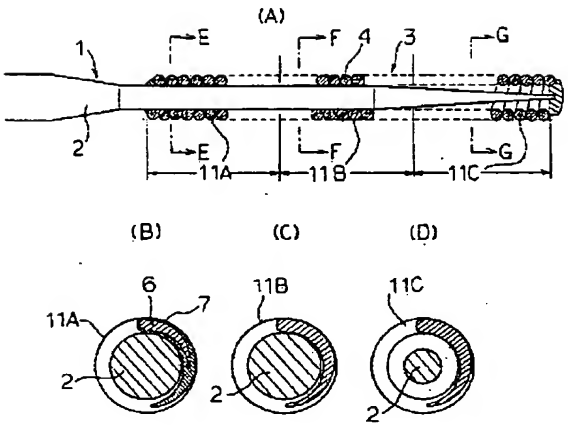
【図３】


(A)
C
2
6
7
10
C
1
7
3
10
(B)
10
6
2
7

【図４】


(A)
C
1
4
3
2
C
2
(B)
6
4
7
11
2

【図５】



【図７】